

FDA Should Not Exclude Accessories from the Scope of the Deeming Rule

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FDA should deem subject to its tobacco control authorities all products meeting the statutory definition of “tobacco product” and should not exclude accessories.

The Family Smoking Prevention and Tobacco Control Act amended Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) by adding the following definition of “tobacco product”:

(rr)(1) The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, *including any component, part, or accessory of a tobacco product* (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). (emphasis added)

The proposed deeming rule correctly acknowledges at FR 23153 that the statutory definition of “tobacco product” includes components, parts, and accessories:

As stated throughout this document, the FD&C Act defines “tobacco product” to include the components, parts, and accessories of such tobacco products (section 201(rr) of the FD& C Act).

FDA adopts this definition of “tobacco product” in the “Definitions” section of Part 1100 of the proposed deeming rule concerning “Tobacco Products Subject to FDA Authority”:

Tobacco product. As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product... (FR 23203, section 1100.3)

Despite the FDA’s clear and correct acknowledgement that the definition of “tobacco product” includes accessories of tobacco products, FDA then ignores its own correct interpretation of the law and proposes to deem and regulate those products meeting the definition of tobacco product, *except* the accessories of proposed deemed products:

Section 1100.1 sets out the scope of FDA’s authority, and states (Option 1):

In addition to FDA’s authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, FDA deems all other products meeting the definition of “tobacco product” under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(rr)), *except accessories of such other tobacco products*, to be subject to the Federal Food, Drug, and Cosmetic Act. [emphasis added] (FR 23202, Section 1100.1, Option 1. (In addition to excluding accessories, Option 2 also excludes certain cigars)

Section 1100.2 provides (Option 1):

Cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and all other tobacco products, *except accessories of such other tobacco products*, are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Tobacco product is defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act. (FR 232023, Section 1100.2, Option 1. [emphasis added] (In addition to excluding accessories, Option 2 also excludes certain cigars)

The proposed rule creates further confusion by providing for contradictory definitions of “covered tobacco product” and “tobacco product” in the “Definitions” section of Part 1140 concerning “Cigarettes, Smokeless Tobacco, and Covered Tobacco Products.” FDA amends the existing section 1140.3 to add the following definitions of “covered tobacco product” and “tobacco product”:

Covered tobacco product means any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act pursuant to section 1100.2 of this chapter, but *excludes any component or part that does not contain tobacco or nicotine.*

...

Tobacco product. As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(rr)) in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, *including any component, part, or accessory of a tobacco product* (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)...” [emphasis added] (FR 23203, 23204, Section 1140.3)

Despite the clear statutory language that explicitly defines “tobacco product” to include accessories, FDA proposed to make an exception for accessories. FDA provides no explanation for why it contradicted the statutory definition of “tobacco product” that it explicitly adopts, and provides no justification for disobeying the clear intent of Congress expressed in the Tobacco Control Act that includes accessories in the definition of “tobacco product.” This inexplicable exception could lead to unnecessary litigation because it not only

creates confusion, but also exceeds FDA's statutory authority under the Tobacco Control Act and is likely unlawful under the Administrative Procedures Act (21 U.S.C. section 706).

These problems were introduced into the proposed rule by the Office of Management and Budget (OMB) and should be remedied by returning to the language that was originally submitted to OMB by the FDA.

As originally drafted by the FDA and submitted to OMB, the proposed rule included accessories within the definition of "tobacco product" in accordance with the Tobacco Control Act. The redlined version of the proposed rule that shows the changes made by OMB¹ reveals that OMB added the exception for accessories.

Indeed, the draft rule that FDA submitted to OMB explained in considerable detail the importance of clarifying the definition of "accessory" to make clear that the regulations would apply to accessories that have "an intended or foreseeable effect on public health."¹ [OMB redline, pp. 139-141] OMB deleted the following language (in the FDA's original proposed rule) that described factors that FDA would consider in determining whether an accessory has an intended or foreseeable effect on public health:

- (1) the characteristics of the underlying tobacco product or the exposure of tobacco product user to chemicals or chemical compounds in the tobacco product, tobacco smoke, vapor, or other byproduct;
- (2) the risk to users or nonusers from exposure to chemicals or chemical compounds in the tobacco product, tobacco smoke, vapor or other byproduct;
- (3) the risks or harms directly or indirectly caused by the tobacco product to users and nonusers, including but not limited to its toxicity, its addictiveness, and its effect on initiation of tobacco use, intensity of tobacco product use (e.g., frequency of use, amount consumed, depth of inhalation), and cessation of tobacco use; and
- (4) perceptions of users and nonusers of the associated harm and risk of disease from the tobacco product, which may affect initiation and cessation of tobacco use.¹ [OMB redline, p. 140]

FDA's original version (also deleted by OMB) also contained the following examples of what likely would and would not be considered an accessory:

An example of an accessory that likely would not be found to have an intended or foreseeable effect on public health would be a simple ashtray that catches the ashes of a cigar or the brush described above. Since these would likely not have a foreseeable effect on the characteristics of the product or on the exposure of the user to chemicals or chemical compounds, these accessories would not fall within the scope of the products over which FDA is extending its tobacco product authorities. In contrast, a filter that imparts additional carcinogens into the tobacco product would fall within the scope of the accessory definition since such a filter would foreseeably affect the characteristics of the product or the exposure of the user to chemicals or chemical compounds. ¹[OMB redline, p. 141]

The changes made by OMB should be reversed; the final rule should use the FDA's original language.

In addition to FDA's example of a filter that imparts additional carcinogens, there are many other accessories associated with existing and newly deemed tobacco products that have an intended or foreseeable effect on public health and therefore should be regulated.

In particular, e-cigarettes rely heavily on separate accessories or components such as tanks and cartridges that contain so-called "e-juice," a liquid that usually contains nicotine, propylene glycol and/or glycerin, and may also contain other substances such as flavorings, caffeine, vitamins, THC, pharmaceuticals, or other chemicals. Moreover, there is wide variability in e-cigarette product engineering, including varying nicotine concentrations in the e-juice that do not always comport with the product's label and varying cytotoxicity² Additionally, exposure to propylene glycol (one of the main base ingredients of most e-juices) can cause eye and respiratory irritation, and prolonged or repeated inhalation in industrial settings may affect the central nervous system, behavior, and the spleen.^{4 3 4 5 6 7 8} An April 2014 CDC study found a dramatic increase in e-cigarette related calls to poison centers.⁹ Poisoning related to e-cigarettes involves the liquid containing nicotine found in the accessories used with the devices, and occur by ingestion, inhalation, or absorption through the skin or eyes.¹¹ More than half of the calls to poison centers due to e-cigarettes involved young children under age 5.¹¹ This situation underscores the need for FDA to have unequivocal authority to regulate these accessories and require childproof containers that are required for other potentially toxic chemicals and pharmaceuticals.

In addition to nicotine poisonings, major injuries and illnesses have resulted from e-cigarette use,¹⁰ including explosions and fires,^{11 12} many of which have been reported to FDA as "adverse events."^{12 13} FDA's report includes 68 adverse events concerning e-cigarettes between 2008 and August 23, 2013, including two deaths.¹⁵ The most common complaints are coughing and respiratory problems, shortness of breath, chest pain, heart irregularities, and dizziness or confusion.¹⁵ Many of these adverse events are related to consumption of chemicals and toxicants contained in e-cigarette cartridges or tanks, further demonstrating that these accessories have foreseeable public health impacts and should be regulated by FDA as part of its tobacco product authorities.

Under the proposed rule as amended by OMB, these containers could evade regulation if they were considered "accessories" rather than components. Restoring the language in the final rule to that originally proposed by the FDA will ensure that these accessories will be regulated.

Another example is hookah, where the charcoal could be an excluded accessory under the proposed rule because it is not "intended or expected to be used by consumers in the consumption of a tobacco product" (FR 23153). However, hookah charcoal combustion is the primary source of carbon monoxide and carcinogenic PAHs¹⁴ as well as benzene exposure, and therefore has a profound public health effect.¹⁵

FDA’s original version of the deeming rule that gave FDA authority to regulate all products that meet the statutory definition of “tobacco product,” including accessories that have “an intended or foreseeable effect on public health,” properly applied the public health standard mandated by Section 906 of the Tobacco Control Act.

OMB should not have added an exception to FDA’s tobacco product authorities for accessories, and should not have deleted the language quoted above.

FDA should return to its original language in the final rule.

¹ OMB Redline CTP20092 4160-01-P, pp. 7-8, 11,22, 137, 139-141. Cite: TAB B Deeming NPRM Redline Changes re Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-20873>

² Grana R, Benowitz N, Glantz S: E-Cigarettes: A Scientific Review. *Circulation*. 2014;129:1972-1986.

³ Sciencelab.com Inc. Material Data Safety Sheet: Propylene Glycol Msds. In: Sciencelab.com Inc., editor. Last updated: 05/21/2013 ed. Houston, TX2013.

⁴ Dow Chemical Company. Product Safety Assessment (Psa): Propylene Glycol. 2013 [November 21, 2013]; Available from: <http://www.dow.com/productsafety/finder/prog.htm#HealthInfo>.

⁵ The American Chemistry Council. Propylene Glycol: Considerations against Use in Theatrical Fogs July 2001: Available from: <http://www.lyondellbasell.com/techlit/techlit/2280.pdf>.

⁶ Laino T, Tuma C, Moor P, Martin E, Stolz S, A. C. Mechanisms of Propylene Glycol and Triacetin Pyrolysis. *The Journal of Physical Chemistry A*. 2012;116:4602-9.

⁷ U.S. EPA. Acrolein. [November 24, 2013]; Available from: <http://www.epa.gov/ttnatw01/hlthef/acrolein.html>.

⁸ Henderson TR, Clark CR, Marshall TC, Hanson RL, CH H. Heat Degradation Studies of Solar Heat Transfer Fluids *Solar Energy*. 1981;27:121-8.

⁹ Centers for Disease Control and Prevention. New CDC study finds dramatic increase in e-cigarette-related calls to poison centers, April 3, 2014. <http://www.cdc.gov/media/releases/2014/p0403-e-cigarette-poison.html>

¹⁰ Chen I-L. FDA Summary of Adverse Events on Electronic Cigarettes. *Nicotine & Tobacco Research*. 2013;15:615-6.

¹¹ CBS NEWS. Electronic Cigarette Explodes in Man’s Mouth, Causes Serious Injuries February 16, 2012: Available from: http://www.cbsnews.com/8301-504763_162-57379260-10391704/electronic-cigarette-explodes-in-mans-mouth-causes-serious-injuries.

¹² Strickland J. Woman Says E-Cigarette Exploded, Shot Flames 4 Feet across Living Room. WSB-TV [serial on the Internet]. 2013: Available from: <http://www.wsbtv.com/news/news/local/woman-says-e-cigarette-exploded-shot-flames-4-feet/nZkCX/>.

¹³ <http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/aboutthecenterfortobacoproducs/ucm361437.pdf>

¹⁴ Monzer B., Sepetdjian E, Saliba N, Shihadeh A. Charcoal emissions as a source of CO and carcinogenic PAH in mainstream narghile waterpipe smoke. *Food Chem. Toxicol*. 2008;46(9):2991-2995.

¹⁵ St. Helen G, Jacob III P, Benowitz NL, FDA Comment: FDA Should Deem Hookah Tobacco, Hookah Device, and Hookah Charcoal as a Tobacco Product, Docket No. FDA-2014-N-0189 (June 27, 2014).